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510 (K) Summary **Section 11**

Submitter's Name / Contact Person

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OCT 16 2009

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Cooper Run Executive Park
575 Route 73 North, Building D
West Berlin, NJ 08091-9293 (USA)

FDA Registration # 2248049

General Information

Trade Name	EP-4™ Cardiac Stimulator
Common / Usual Name	External Programmable Pacemaker Pulse Generator
Classification Name	JOQ, Class II, 21 CFR 870.1750
Predicate Device	EP-4™ Clinical Stimulator (K040207)

Device Description

The EP-4 Cardiac Stimulator consists of a touch-screen computer, an AC-powered stimulation module, which provides electrical stimulation to the heart during electrophysiology case studies. The EP-4 consists of a touch-screen computer that controls a two- or four-channel AC-powered stimulation module, and a keyboard. The stimulator is capable of performing single channel, simultaneous, or sequential stimulation at programmed output settings using existing/predicate programmed protocols.

The device is independent and self-contained, with the exception of marker outputs and an external sync input connector. It can be configured as a stand-alone system or in conjunction with the EP-WorkMate™ Recording System. It may also be used with other EP recording systems.

Key features of the EP-4 Cardiac Stimulator are:

- Available in stand-alone configuration or integrated to the EP-WorkMate™ Recording System
- Compact and portable in stand alone configuration
- Touch screen display or color-coded keyboard user interface
- Initiate and terminate pacing manually or by a pre-programmed automatic mode
- Available in two- or four-channel versions
- Pre-programmed protocols include SNRTs, overdrive and arrhythmia induction
- Up to 10 user-defined protocols can be stored in memory
- Parameters can be changed with a single keystroke or touch screen button

Software Description

The EP-4 Cardiac Stimulator functions are controlled by the system software. The menu-driven software is controlled through a user interface with a touch-screen computer or keyboard. The software architecture includes the system software and firmware in the mother, stimulator, and trigger boards.

Hardware Description

The EP-4 Cardiac Stimulator hardware consists of a touch-screen computer, an AC-powered stimulation module and a keyboard. The device may also be integrated into an EP-WorkMate recording system or used with other electrophysiology recording systems.

A graphical presentation of system interconnections is provided in Figure 2.

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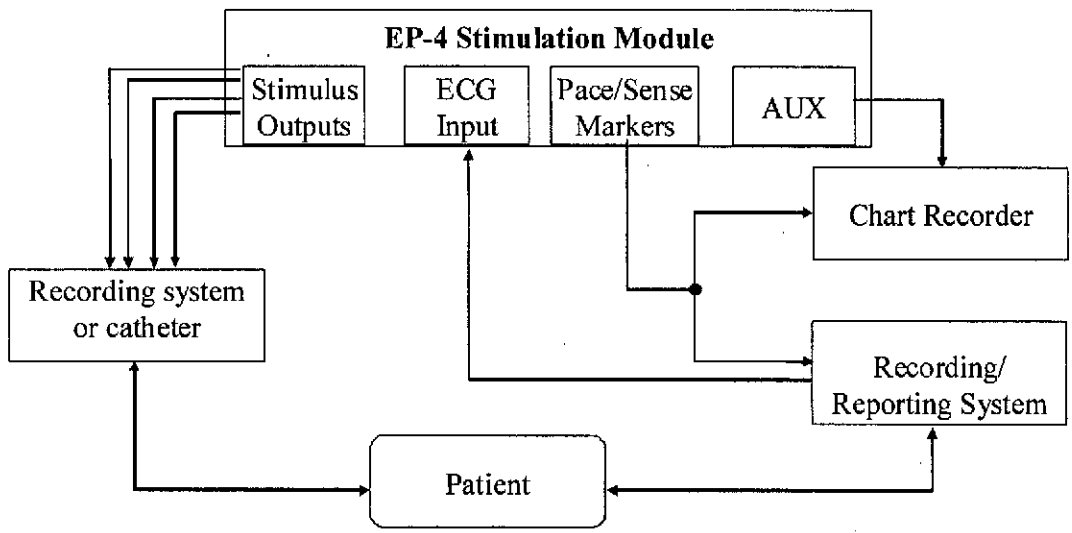

Figure 2: EP-4 Cardiac Stimulator Interconnection Diagram

Indications for Use

The EP-4 Cardiac Stimulator is indicated for use during clinical cardiac electrophysiology procedures.

Intended Use

The EP-4 Cardiac Stimulator is intended to be used for diagnostic electrical stimulation of the heart for the purpose of refractory measurements, initiation and termination of tachyarrhythmias, and measurements of electrical conduction.

Device Comparison to the Cleared Device

The EP-4 Cardiac Stimulator has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the EP-4 are substantially equivalent to the predicate device.

Summary of Non-Clinical Testing

Bench testing was performed to confirm that the changes met design requirements and did not adversely affect the safety or efficacy of the product.

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Summary of Design Control Activities

The development of EP-4 design modifications was performed in accordance with St. Jude Medical's Quality System requirements, and in compliance with Quality System Regulation design controls requirements documented in 21 CFR 820.30.

Conclusion

The EP-4 Cardiac Stimulator has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the EP-4 Cardiac Stimulator are substantially equivalent to the predicate device.

Where design differences exist between the proposed device and the predicate device, performance testing demonstrated that these differences do not adversely affect the device's safety and effectiveness.

Therefore, St. Jude Medical considers the EP-4 Cardiac Stimulator to be substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Ms. Sushma Rao
Regulatory Specialist
575 Route 73 North Building D
West Berlin, NJ 08091

OCT 1 6 2009

Re: K092913
Trade/Device Name: EP-4™ Cardiac Stimulator
Regulatory Number: 21 CFR 870.1750
Regulation Name: Pulse Generator, Pacemaker, External Programmable
Regulatory Class: II (two)
Product Code: 74 JOQ
Dated: September 18, 2009
Received: September 22, 2009

Dear Mr. Jung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K092913

INDICATIONS FOR USE STATEMENT Section 6

INDICATIONS FOR USE

510(K) Number (if known): _____

Device Name: EP-4™ Cardiac Stimulator

Indications for Use

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Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off) 10/16/09

Division of Cardiovascular Devices

510(k) Number K092913